Program Priorities in the Center for Drug Evaluation and Research; Public Meeting
[Docket No. 98N-0339]

Request for Comments

August 17, 1998

Comments on Behalf of the Association of Food and Drug Officials (AFDO)
Cynthia Culmo, Chair
Drugs, Devices, and Cosmetics Committee

Good morning everyone. My name is Cynthia Culmo and I am the Director, Drugs and Medical Devices Division, Texas Department of Health. I currently serve as the Chair of the Drugs, Devices, and Cosmetics Committee of the Association of Food and Drug Officials (AFDO.) We are pleased to be able to present comments this morning regarding a most important endeavor and challenge for FDA, and we consider AFDO to be an important FDA stakeholder in this process.

Before I address each of the specific CDER questions, for those of you that may not be familiar with AFDO, I would like to explain who "we" are and explain our mission. AFDO is a nonprofit professional association consisting of state, federal, and local regulatory officials as members, with industry representatives participating as associate members. From its very inception more than 102 years ago, AFDO has recognized the need for consumer protection and uniformity of regulation. AFDO was established in 1896, and successfully fosters uniformity in the adoption and enforcement of food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO provides the mechanism and the forum where regional and national issues are deliberated and resolved uniformly to provide the best public health and consumer protection in the most expeditious and cost-effective manner. Through its six regional affiliates a partnership process has been created which has resulted in the significant improvement of consumer protection in our country. Uniformity is achieved by education, communication and cooperation among the states. We routinely provide comments to federal agencies on public health matters such as those before us today.

AFDO depends upon, and extensively associates with, the leadership of FDA, and specifically with the centers. Its members work closely with CDER and rely upon their expertise and guidance. CDER requested that stakeholders address six specific questions and any other objectives related to the agency's statutory obligations or public expectations. The suggestions we offer are a result of current concerns of state and local regulators. It's important to remember that state and local regulatory officials, as well as industry must act immediately to address complaints, illnesses, injuries and trends, even if it means developing interim policies. Time may be useful in developing strategies during debate, but it is a curse for those who must act immediately.

Accordingly, AFDO is pleased to offer the following comments concerning CDER's questions:

Drug Marketing and Advertising

AFDO recognizes the importance and yet difficult task this challenge presents. AFDO believes the best direction for this oversight would be through the utilization of a consumer panel

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to assess reactions to advertisements. Reviews should be utilized both prior to the public advertising and post advertisement. Do not depend upon scientists to review direct consumer advertising. Additionally it would seem that "appropriate messages" needs to be defined, and recognize this could be different for individual drugs. Solicit input and directions from healthcare professionals and the ethnic communities.

Inspections

There is still confusion regarding CDER inspections and FIELD inspections. It is our understanding that the field inspectors respond to CDER, yet there is still evidence these are separate inspections. There needs to be a clearer understanding of CDER's relationship to the Districts and Regions, a relationship that should be communicated down to the consumer's level, or at least to the State and local regulatory level.

Other appearances are that CDER directs inspections to the user fee activity - NDA's, and not the complete inspection. It's a product specific inspection. We would suggest more time be devoted to the inspection process to allow for a more comprehensive inspection. The District inspections are directed to the "black & white" of the regulations, not the health impact of the regulations. Example being, process validation - it's theoretically based. How are smaller companies to comply? Is every aspect of process validation critical in a smaller company with one simple product? Current FDA inspections could be improved if augmented by the states' inspectional data, resources, and partnerships that included the continuation of the state contracts.

Realizing this would require improved resources and budgets, it would still seem appropriate to perform periodic quality assurance inspections and laboratory analyses for identity, potency, and purity to ensure the quality of drugs manufactured in foreign establishments. In this same realm, partnerships are only as effective as the regulatory program and standards in each country. While the MRA is attempting an honorable and desirable result, we would like to stress that the foreign countries should have not only equivalent standards, but effective regulatory programs as well. FDA could expend more time in foreign oversight and utilize the states to cover domestic regulatory oversight at their level.

Drug Information

FDA is known for providing regulatory information on drugs, not for the patient information. It's this information for the consumers, as well as the clinical trials information to the regulatory and healthcare professionals that AFDO believes could be improved. Currently, the regulatory and healthcare professionals must search and seek published information. Many are utilizing and depending upon the Internet for these purposes, and we believe many consumers are also adept at searching the Internet for their drug information. This brings to question the validity and integrity of that information -- but, that's another subject for another discussion.

Methods that AFDO believes effective in improving communications and improving information dissemination are FDA articles in professional journals, Internet messages, consumer articles in all news media -- radio and television advertisements (episodes of the Simpsons, since Seinfeld is gone?), consumer magazines, and health and/or trade magazines. Information in some format, placed in the physicians' offices, patients' rooms in hospitals, and emergency rooms for consumer access would be an improvement. Improved access to package inserts for both public and regulators would be appreciated. A FDA Internet board could be a cost-effective way to provide the information to many of these entities.

Surveillance and Adverse Event Reporting

We believe emphasis should be directed to decreasing the number of adverse events, and then secondarily concentrate on the passive reporting system for adverse events. Although, we acknowledge that the two systems are intertwined. If information is increased to the consumers, professionals, and regulators, and there is an increase in effort and expediency in removing harmful drugs from commerce, then we would expect the number of adverse events to decrease. Consideration should also be given to mandatory reporting in hospitals similar to the Medical Device Reporting requirements.

By increasing resources in CDER, priority given to the MedWatch system, and better utilization of assets available in the states could result in improved response to death and injuries from medicines. Additionally, the FDA might consider regular continuous reminders to healthcare professionals and regulators. It's not uncommon too only receive one message from FDA on a critical outcome associated with a drug, and most people need more than one notice to "associate" or "recall." AFDO also believes that one improvement in the MedWatch reports would be to better exchange information with the states. Such as, reports to the states on a continuous basis, and the states report to FDA on a continuous basis as well.

Balance

Premarket review should be emphasized. Postmarket surveillance may be strengthened through use of the states' resources and the consideration of drug reporting requirements similar to the medical devices reporting requirements.

Priorities

Highest priority should be to continue to improve the drug approval process. The expedited removal of unsafe products is also critical.

Next the review of the "grandfathered" drugs, such as ephedrine, which were never subjected to a drug approval process should be completed. This could lead to improved monographs and result in the much needed reclassification of some drugs. Over-the counter monographs need to be finalized too, with periodic reviews to update and clarify the finalized monographs pursuant to new technologies and drugs. Additionally, CDER should consider nontraditional drugs and ethnic use in these monographs or as a new category of medicines.

AFDO emphasizes greater interaction with the states to include joint work planning in areas of shared responsibilities. There are several models for this in the FDA Regional offices which could serve the Centers.

Imports definitely need attention. We know there are alleged compliance and equivalency of standards, yet the states continue to receive complaints and inquiries concerning inferior import products. The "personal use" policy should be reviewed and updated due to concerns and complaints related to the quality of these products and the probability of diversion into normal commerce.

Once again, we would like to express our appreciation for the opportunity to provide comments on Program Priorities in the Center for Drug Evaluation and Research. As a stakeholder, we are prepared to work with FDA to improve the CDER processes.